**U.S. Department of Justice**

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January 19, 2021

**BY ECF**
The Honorable Mary Kay Vyskocil
United States District Judge
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, New York 10007

Re: *Pfizer Inc. v. United States Department of Health and Human Services, et al.*, No. 20 Civ. 4920 (MKV)

Dear Judge Vyskocil:

This Office represents the defendants (the "Government") in the above-referenced action. We write respectfully to respond to the supplemental letter brief filed by Plaintiff Pfizer Inc. ("Pfizer") on December 30, 2020 (ECF No. 58) ("Pfizer Ltr.").

In its letter brief, Pfizer mischaracterizes the district court's opinion in *United States v. Regeneron Pharma., Inc.*, No. 20-11217, 2020 WL 7130004 (D. Mass. Dec. 4, 2020), which held that allegations that a pharmaceutical manufacturer indirectly provided copay assistance with the intent to induce the purchase of its drug—"subverting [Medicare Part B's] copay requirement," which creates "an incentive to choose the most cost-effective treatment," *id.* at *1—stated a claim under the Anti-Kickback Statute (AKS) and the False Claims Act. *Id.* at *7-16.

Like Pfizer has here, defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") argued that an AKS violation requires corruption of clinical decision-making. *Id.* at *11. And—like Pfizer has here—Regeneron insisted its copay assistance "did not improperly influence decisions on . . . health care, because [its drug] was the best clinical choice." *Id.* (internal quotation marks omitted). The court expressly rejected this argument, explaining that, "to state an AKS violation, the complaint need not allege that the kickbacks actually corrupted clinical-decision making or provide 'proof that the underlying medical care would not have been provided but for a kickback.'" *Id.* (quoting *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3d Cir. 2018)). Indeed, the court recognized that the only "improper purpose" required by the AKS is the intent "to induce Medicare or Medicaid patient referrals" or purchases. *Id.* at *8 (internal quotation marks omitted); *accord id.* at *11-12. As alleged, Regeneron—like Pfizer in this case—intended to induce referrals or purchases of its drug "by removing

financial considerations" through its copay assistance program; that violated the AKS. *Id.* at *11.

Pfizer also misconstrues language in the preamble to a rule recently issued by OIG, which, among other things, created new AKS safe harbors and modified certain existing safe harbors. *See* 85 Fed. Reg. 77684 (Dec. 2, 2020). To determine whether a given financial arrangement violates the AKS, OIG's longstanding practice is to analyze first whether the AKS is implicated, *i.e.*, whether there is remuneration and, *inter alia*, the purchase of or referral for a covered item or service. If so, the OIG next determines whether the arrangement fits within any of the statutory exceptions or regulatory safe harbors. If the AKS is implicated and the arrangement does not fit within an exception or safe harbor OIG considers whether, considering the totality of the facts and circumstances, one purpose for the remuneration was to induce that purchase or referral. If so, then the arrangement violates the AKS.

In keeping with that analysis, OIG recognized in its recent rulemaking that "beneficial arrangements might implicate the statute (for example, the arrangement might involve parties that are exchanging something of value and are in a position to refer Federal health care program business between them) but [] not fit in . . . [the] available safe harbors." *Id.* at 77685. That is, a financial arrangement might include remuneration and the purchase of or referral for a covered item or service and not fit within an exception or safe harbor, in which case the question of its legality under the AKS turns on whether, considering the totality of the facts and circumstances, it is determined that one purpose of the remuneration was to induce the purchase or referral. Thus, OIG noted: "Arrangements are not necessarily unlawful because they do not fit in a safe harbor. Arrangements that do not fit into a safe harbor are analyzed for compliance with the [AKS] based on the totality of their facts and circumstances, including the intent of the parties." *Id.*

Pfizer misreads this language, mistakenly believing OIG's reference to arrangements that "might implicate the statute," *id.*, to mean arrangements with the intent to induce a covered purchase or referral, when OIG is in fact referring to arrangements that include the provision of remuneration and covered purchases or referrals *before* intent is determined. Based on that error, Pfizer suggests that OIG, *sub silentio*, broke from its decades-long interpretation of the AKS and, in a stray sentence, for the first time took the position that the provision of remuneration with the intent to induce a covered purchase or referral outside a safe harbor is not "necessarily" prohibited by the AKS. Pfizer Ltr. 2. Pfizer is mistaken.

Pfizer likewise misinterprets a single-sentence gloss on the AKS in this summary—which correctly notes that the AKS bars "intentional payments . . . in exchange for referrals," 85 Fed. Reg. at 77684—as a statement of the full scope of the AKS. Pfizer Ltr. 2. Again, OIG did not, *sub silentio*, change its longstanding position that a *quid pro quo* is not required to violate the AKS. *Accord* ECF No. 45, Govt's Opp. Br. 19-20 (collecting cases); *Regeneron*, 2020 WL 7130004, at *11.

We thank the Court for its attention to this matter.

Respectfully submitted,

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